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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,365	11/12/2001	Carol W. Readhead	18810-81606	9234

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,365	READHEAD ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *135-144,152-161 and 168-176* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *135-144,152-161 and 168-176* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of 09/191,920, filed November 13, 1998, which claims benefit to provisional application 60/065,825 filed November 14, 1997.

Applicants' amendment filed January 9, 2004, has been received and entered. Claims 145-151, 162-167 and 177-182 have been canceled. Claims 144 and 168 have been amended. Claims 135-144, 152-161 and 168-176 are pending.

Election/Restriction

Applicant's election of Group I, claims 145-151, 162-167 and 177-182, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted that claims drawn to a the non-elected inventions have been canceled. Claims 135-144, 152-161 and 168-176 are pending and currently under examination as they are drawn to a non-human transgenic vertebrate.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i). Claims 135-144, 152-161 and 168-176 are pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 152 and 168 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 152 is unclear in the recitation of "encoding a desired trait" because genes encode proteins not traits. A particular phenotype may result as a consequence of a genes expression, but the gene does not encode a trait or phenotype.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 135-144, 152-161 and 168-176 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 135 of copending Application No. 10/074,945. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed transgenic vertebrates would necessarily result in practicing the method of claim 135. For example, claim 168

specifically recites the same method steps of claim 135. It is noted that the preamble of claim 135 is generally directed to gene therapy, however the outcome and animal that results from practicing the claimed method would inherently be the same as instantly claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims135-144, 152-161 and 168-176 are rejected under 35 U.S.C. 102(e) as being anticipated by Brinster *et al.* (US Patent 5,858,354).

Claims 135-144, 152-161 and 168-176 are broadly drawn to a non-human transgenic vertebrate. It is noted that the transgenic vertebrate are generated as product by process, however these process steps do not exclude transgenic animals made by other means. Brinster *et al.* teaches a method for making a genetically altered transgenic animal wherein germ cells are genetically altered *in vitro* an subsequently transplanted back into the seminiferous tubules. The allowed claims specifically set forth transducing the cell type of spermatogonia, however the

specification provides for other male germ cells to be collected and used in the claimed methods. Practicing the methods claimed by Brinster *et al.* result in a transgenic animal comprising germ cells that have been genetically modified with a transgene.

Where, as here, the claimed and prior art products are identical or substantially identical, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102, or "*prima facie* obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw,* 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Claims 135-144, 152-161 and 168-176 are rejected under 35 U.S.C. 102(e) as being anticipated by Deboer *et al.* (US Patent 5,741,957).

Deboer *et al.* teach a method of making a transgenic bovine whose genome comprises an transgene that is preferentially expressed in the mammary gland (see abstract). It is noted that the methods of Deboer *et al.* result in a transgenic animal in which both the germ cells and somatic cells contain the transgene, however the instantly pending claims do not exclude this possibility. Importantly, dependent claims directed to progeny will necessarily comprise the transgene in both the somatic cells and germ cells if produced by mating.

Claims 135-144, 152-161 and 168-176 are rejected under 35 U.S.C. 102(b) as being anticipated by Leder *et al.* (US Patent 4,736,866).

Leder *et al.* teach a method of making non-human transgenic mammals whose genome comprises an activated oncogene (see abstract). It is noted that the methods of Leder *et al.* result in a transgenic animal in which both the germ cells and somatic cells contain the transgene, however the instantly pending claims do not exclude this possibility. Moreover, dependent claims directed to progeny will necessarily comprise the transgene in both the somatic cells and germ cells if produced by mating.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6,215,039 (Brinster *et al.*) is related to US Patent 5,858,354 and provides the same guidance at the '354 patent used in the basis of the rejection made under 35 USC 102(e) set forth above.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach